

CLAIMS

What is claimed is:

1. A prosthesis having a bifurcation for repairing an aortic aneurysm close to or involving the aortic bifurcation having an arterial wall and comprising the aorta and the first and second iliac arteries extending therefrom and in fluid communication therewith in a patient, the prosthesis comprising:

a main tubular body;

first and second tubular legs joined to said main tubular body in a bifurcation, said main tubular body and said first and second tubular legs being formed of a flexible surgically implantable material, said main tubular body and said first and second tubular legs having respectively first, second and third openings therein in fluid communication with each other;

first expandable attachment means for anchoring said main tubular body, said first attachment means being secured to said main tubular body adjacent the first opening;

second expandable attachment means for anchoring said first tubular leg, said second attachment means being secured to said first tubular leg adjacent the second opening; and

third expandable attachment means for anchoring said second tubular leg, said third attachment means being secured to said second tubular leg adjacent the third opening,

wherein said prosthesis is capable of intraluminal implantation by a catheter into the aortic bifurcation through the first iliac artery such that said main tubular body can be anchored by said first attachment means in the aorta, said first tubular

leg can be anchored by said second attachment means in the first iliac artery, and said second tubular leg can be anchored by said third attachment means in the second iliac artery.

2. A prosthesis as in claim 1, wherein said first, second and third attachment means are each in the form of a self-expanding attachment system having outwardly disposed wall engaging members.

3. A prosthesis as in claim 1, wherein said main tubular body includes a plurality of radiopaque markers spaced longitudinally along said main tubular body, such that twisting of the main tubular body may be detected by viewing the radiopaque
5 markers by fluoroscopy.

4. A prosthesis as in claim 1, further comprising a plurality of longitudinally spaced apart radiopaque markers carried by each of said first and second tubular legs, wherein twisting of said tubular legs may be detected by viewing said
5 radiopaque markers by fluoroscopy.

5. An intraluminal graft deployed using a catheter in the vasculature of a patient, the intraluminal graft comprising:
support means for reinforcing a vasculature of a patient, said support means having a main tubular member, a first
5 tubular leg and a second tubular leg in fluid communication with the vasculature;

-66-

a plurality of anchoring means for attaching the main tubular member, the first tubular leg and the second tubular leg to the vasculature; and

means for resisting kinking in the first tubular leg
5 and in the second tubular leg.

6. The intraluminal graft of claim 5, wherein said means for resisting kinking comprises a plurality of crimps configured in the first tubular leg and in the second tubular leg.

7. The intraluminal graft of claim 5, wherein said means for resisting kinking comprises at least one medial attachment system secured within the first tubular leg and at least one medial attachment system secured within the second tubular leg.

8. An intraluminal graft for permanent implantation in a patient's vasculature for repairing the vasculature proximate to a bifurcation in the vasculature, the intraluminal graft being intraluminally deployed into the vasculature using a catheter,
5 the intraluminal graft comprising:

a main tubular body having a superior end and configured to reside proximate a bifurcation in a vasculature of a patient, the bifurcation forming a first vessel and a second vessel;

10 a first tubular member having an inferior end and joined to and in fluid communication with said main tubular body, said first tubular member configured to extend into the first vessel;

-67-

a second tubular member having an inferior end and joined to and in fluid communication with said main tubular body, said second tubular member configured to extend distally into the second vessel;

5 a first attachment system secured to the superior end of said main tubular body;

a second attachment system secured to the inferior end of said first tubular member; and

a third attachment system secured to the inferior
10 end of said second tubular member.

9. The intraluminal graft of claim 8, further comprising a plurality of crimps configured in the first tubular member and in the second tubular member.

10. The intraluminal graft of claim 8, wherein said first attachment system, said second attachment system and said third attachment system each include a plurality of support members and a plurality of wall engaging members, each support member
5 having two legs joined to form an apex, each leg being joined to the legs of adjacent support members to form a circular arrangement of support members about a central axis and operable between a first collapsed position and a second expanded position.

-68-

11. The intraluminal graft of claim 10, wherein the support members of said attachment systems further include a first helical spring and a second helical spring.

12. The intraluminal graft of claim 8, wherein the support members of said attachment systems are formed from a non-round wire.

13. The intraluminal graft of claim 8, further comprising means for reducing blood leakage near the superior end of the main tubular body.

14. The intraluminal graft of claim 13, wherein said means for reducing blood leakage near the superior end of the main tubular body is formed from a segment of biocompatible fiber.

15. A system for implanting a prosthesis in a corporeal lumen having a wall, said system comprising:

a bifurcated graft having a superior end, an ipsilateral inferior end and a contralateral inferior end, said bifurcated
5 graft having an attachment system located at each of the superior and inferior ends;

a capsule catheter having an elongate tubular member having proximal and distal ends, said capsule catheter having an ipsilateral capsule positioned at the distal end of the elongate
10 tubular member;

a balloon catheter disposed within said capsule catheter, said balloon catheter including a second elongate tubular member

-69-

having proximal and distal ends, an inflatable member positioned proximal the distal end of the second elongate tubular member, and a distal capsule positioned proximate the distal end of the second elongate tubular member; and

5 a contralateral capsule assembly positionable proximate the ipsilateral capsule of said capsule catheter, said contralateral capsule assembly including a contralateral capsule, wherein the superior end of said bifurcated graft is removably retained in the distal capsule, the ipsilateral
10 inferior end is removably retained in the ipsilateral capsule and the contralateral inferior end is removably retained in the contralateral capsule.

16. The system as recited in claim 15, further comprising a capsule jacket slidably positioned coaxially with said capsule catheter and said balloon catheter, wherein the capsule jacket is of sufficient length to cover the ipsilateral capsule, the
5 contralateral capsule and at least a portion of the distal capsule.

17. The system as recited in claim 15, further comprising:
a control wire slidably disposed in a lumen of the second elongate tubular member, the control wire having a proximal end and a distal end secured to the distal capsule; and
5 control means connected to the proximal end of the control wire for moving the distal capsule relative to the second elongate tubular member.

18. The system as recited in claim 17, wherein said balloon catheter further comprises a proximal cap secured to the second elongate tubular member, wherein the proximal cap is configured and positioned to be slidably retained within the
5 distal capsule.

19. The system as recited in claim 15, wherein said contralateral capsule assembly further includes a guiding tube having a distal end secured to the contralateral capsule and a pull wire disposed within a lumen of the guiding tube, wherein
5 the pull wire has a distal end configured with a locking ball for retaining within the contralateral capsule the attachment system located at the contralateral inferior end of the bifurcated graft.

20. The system of claim 15, wherein said balloon catheter further comprises retaining means for engaging the attachment system located at the ipsilateral inferior end of said bifurcated graft, the retaining means being slidably disposed on the second
5 elongate tubular member proximal the inflatable member.

21. The system of claim 20, wherein said balloon catheter further comprises locking means fixedly positioned on the second elongate tubular member proximal the retaining means for preventing longitudinal movement of the retaining means.

-71-

22. A system for implanting a prosthesis proximate an aortic bifurcation having an aneurism, said system comprising:

a bifurcated graft having a superior end, an ipsilateral inferior end and a contralateral inferior end, said bifurcated
5 graft having an attachment system located at each of the superior and inferior ends;

a capsule catheter having an elongate tubular member having proximal and distal ends, said capsule catheter having an ipsilateral capsule positioned at the distal end of the elongate
10 tubular member;

a balloon catheter disposed within said capsule catheter, said balloon catheter including a second elongate tubular member having proximal and distal ends, an inflatable member positioned proximal the distal end of the second elongate tubular member,
15 and a distal capsule positioned proximate the distal end of the second elongate tubular member;

a contralateral capsule assembly positionable proximate the ipsilateral capsule of said capsule catheter, said contralateral capsule assembly including a contralateral capsule; and

20 a capsule jacket slidably positioned coaxially with said capsule catheter and said balloon catheter and covering at least a portion of said contralateral capsule assembly, wherein said capsule jacket is of sufficient length to cover both the ipsilateral capsule and at least a portion of the distal capsule such
25 that the superior end of said bifurcated graft is removably retained in the distal capsule, the ipsilateral inferior end is removably retained in the ipsilateral capsule and the contra-

lateral inferior end is removably retained in the contralateral capsule.

23. A system for placing a bifurcated graft in a lumen formed by a wall proximate an aortic bifurcation having an aneurism, said system comprising:

a bifurcated graft having a superior extremity, an ipsi-
5 lateral inferior extremity and a contralateral inferior
extremity, said bifurcated graft being deformable between a
collapsed condition and an expanded condition;

first anchoring means secured to the superior extremity
of said bifurcated graft for attaching the superior extremity
10 of said bifurcated graft to the lumen wall;

second anchoring means secured to the ipsilateral inferior
extremity of said bifurcated graft for attaching the ipsilateral
inferior extremity of said bifurcated graft to the lumen wall;

third anchoring means secured to the contralateral inferior
15 extremity of said bifurcated graft for attaching the contra-
lateral inferior extremity of said bifurcated graft to the lumen
wall;

a distal capsule assembly for covering said first anchoring
means;

20 an ipsilateral capsule assembly for covering said second
anchoring means;

a contralateral capsule assembly for covering said third
anchoring means, wherein at least a portion of said bifurcated
graft between said first, second and third anchoring means
25 remains uncovered by the capsules;

-73-

a removable sleeve of a flexible material, said removable sleeve configured to extend over said inferior capsule assembly, said bifurcated graft and at least a portion of said contralateral capsule assembly and said distal capsule assembly, wherein a smooth transition is provided between said ipsilateral capsule assembly, said contralateral capsule assembly and said distal capsule assembly;

a first catheter including a balloon secured to a first flexible elongate shaft having an inflation lumen in fluid communication with the balloon, said first catheter being capable of moving the balloon within said bifurcated graft and into engagement with said first anchoring means and with said second anchoring means;

a control wire having a proximal end and a distal end secured to the distal capsule assembly, the shaft of the first catheter being provided with a control wire lumen for slidably retaining the control wire, wherein the distal capsule assembly moves relative to the shaft by movement of the proximal end of the control wire; and

a second catheter including a second flexible elongate shaft having a proximal end positioned distal the proximal end of the first shaft of said first catheter and having a distal end secured to the ipsilateral capsule assembly, such that movement of said second catheter may move said ipsilateral capsule assembly without moving said distal capsule assembly,

wherein the first shaft of said first catheter is coaxially disposed within the second shaft of said second catheter, said

removable sleeve being coaxially disposed over both the first shaft the second shaft.

24. The system as recited in claim 23, wherein said contralateral capsule assembly further includes a contralateral capsule, a guiding tube having a distal end secured to the contralateral capsule and a pull wire disposed within a lumen
5 of the guiding tube, wherein the pull wire has a distal end configured with a locking ball for retaining the third anchoring means within the contralateral capsule.

25. A method for securing a bifurcated graft in a corporeal lumen, the bifurcated graft having a superior end, an ipsilateral inferior end and a contralateral inferior end, the bifurcated graft further having a superior attachment system
5 disposed proximate the superior end, an ipsilateral attachment system disposed proximate the ipsilateral inferior end and a contralateral attachment system disposed proximate the contralateral inferior end, said method comprising the steps of:

providing a delivery catheter assembly having distal
10 capsule means for containing the superior attachment system of the bifurcated graft, ipsilateral capsule means for containing the ipsilateral attachment system and contralateral capsule means for containing the ipsilateral attachment system;

positioning the delivery catheter assembly and the
15 bifurcated graft at a desired location within a corporeal lumen;

-75-

withdrawing the distal capsule means from the superior end of the bifurcated graft to expose the superior attachment system;

5 withdrawing the contralateral capsule means from the contralateral inferior end of the bifurcated graft to expose the contralateral attachment system;

withdrawing the ipsilateral capsule means from the ipsilateral inferior end of the bifurcated graft to expose the ipsilateral attachment system; and

10 removing the delivery catheter from the corporeal lumen, wherein the bifurcated graft remains secured within the corporeal lumen.

26. The method of claim 25, wherein the positioning step includes placing the bifurcated graft proximate an aneurism proximate an aortic bifurcation.

27. A method for emplacement of a bifurcated graft in a corporeal lumen having a wall, the bifurcated graft having a plurality of attachment systems and being disposed within a delivery catheter assembly including a balloon catheter having
5 a distal capsule, an inflatable member and a first shaft coupled to the distal capsule and the inflatable member, the delivery catheter assembly further including a capsule catheter having an ipsilateral capsule and second shaft coupled to the ipsilateral capsule, the delivery catheter further including a
10 contralateral capsule assembly having a contralateral capsule, said method comprising the steps of:

-76-

manipulating the delivery catheter assembly to advance the bifurcated graft, the balloon catheter, the capsule catheter and the contralateral capsule into a corporeal lumen, wherein the bifurcated graft and each attachment system are removably
5 retained in the distal, ipsilateral and contralateral capsules to prevent the attachment systems from contacting the corporeal lumen wall while the bifurcated graft is being advanced through the corporeal lumen;

positioning the bifurcated graft at a desired location
10 in the corporeal lumen;

removing the attachment systems from the distal, ipsilateral and contralateral capsules;

inflating the inflatable member to engage at least one attachment system of the bifurcated graft so that the attachment
15 system and the bifurcated graft are secured to the corporeal lumen wall;

deflating the inflatable member; and

withdrawing the delivery catheter assembly from the bifurcated graft and from the corporeal lumen, wherein the
20 bifurcated graft is retained within the corporeal lumen.

28. The method of claim 27, wherein the delivery catheter assembly further includes a capsule jacket coaxially disposed over the capsule catheter, and the balloon catheter is coaxially disposed within the capsule catheter, such that the capsule
5 jacket covers the bifurcated graft, the ipsilateral capsule, the contralateral capsule and at least a portion of the distal capsule, said method further comprising the step of withdrawing

-77-

the capsule jacket from the bifurcated graft prior to removing the attachment systems from the distal, ipsilateral and contralateral capsules.

29. A method for implanting a bifurcated graft in a corporeal lumen having a wall afflicted by an aneurysm having a superior end, the bifurcated graft including a superior attachment system having wall engaging members, an ipsilateral
5 attachment system having wall engaging members and a contralateral attachment system having wall engaging members, said method comprising the steps of:

covering the ipsilateral attachment system of the bifurcated graft with an ipsilateral capsule, the ipsilateral
10 capsule being coupled to a first shaft;

covering the superior attachment system of the bifurcated graft with a distal capsule, the distal capsule being coupled to a second shaft in fluid communication with a main balloon, wherein the second shaft is coaxially and slidably disposed
15 within the first shaft;

covering the contralateral attachment system of the bifurcated graft with a contralateral capsule, the contralateral capsule being coupled to a pull wire;

covering the bifurcated graft, the ipsilateral capsule, the contralateral capsule and at least a portion of the distal capsule and pull wire with a sheath slidably disposed over the first and second shafts;

introducing the bifurcated graft, distal capsule, ipsilateral capsule, contralateral capsule, pull wire, balloon and

-78-

at least a portion of the first shaft, second shaft and sheath into a corporeal lumen;

positioning the bifurcated graft such that the superior attachment system is located superior to the superior end of the
5 aneurysm;

removing the sheath from the distal capsule, the contralateral capsule and at least a portion of the ipsilateral capsule;

removing the distal capsule from the superior attachment
10 system;

positioning the main balloon adjacent the superior attachment system;

inflating the main balloon to urge the wall engaging members of the superior attachment system into the wall of the
15 lumen;

removing the contralateral capsule from the inferior attachment system and from the corporeal lumen;

inserting an auxiliary balloon into the corporeal lumen adjacent the contralateral attachment system;

20 inflating the auxiliary balloon to urge the wall engaging members of the contralateral attachment system into the wall of the lumen;

removing the ipsilateral capsule from the ipsilateral attachment system;

25 deflating the auxiliary balloon;

removing the auxiliary balloon from the corporeal lumen;

deflating the main balloon;

-79-

positioning the main balloon adjacent the ipsilateral attachment system;

inflating the main balloon to urge the wall engaging members of the ipsilateral attachment system into the wall of
5 the lumen;

deflating the main balloon; and

removing the main balloon, distal capsule, ipsilateral capsule, first shaft, second shaft and sheath from the corporeal lumen, wherein the bifurcated graft is retained in the lumen.

30. The method of claim 29, wherein said introducing the bifurcated graft step includes providing an opening in at least one femoral artery and said positioning the bifurcated graft step includes placing the bifurcated graft proximate an aortic
5 bifurcation.

31. A method for engrafting a bifurcated prosthesis into a corporeal lumen, the bifurcated prosthesis having a superior end, an ipsilateral end and a contralateral end, the bifurcated prosthesis further having a superior attachment system at the
5 superior end, an ipsilateral attachment system at the ipsilateral end and a contralateral attachment system at the contralateral end, said method comprising the steps of:

(a) providing delivery means for positioning a bifurcated prosthesis in a corporeal lumen, wherein the delivery means comprises distal capsule means for removably
10 retaining a superior attachment system, ipsilateral capsule means for removably retaining an ipsilateral

-80-

attachment system and contralateral capsule means for removably retaining a contralateral attachment system;

- 5 (b) providing capsule jacket means for removably retaining the bifurcated prosthesis, distal capsule means, ipsilateral capsule means and contralateral capsule means;
- (c) placing the superior attachment system of the bifurcated prosthesis into the distal capsule means;
- 10 (d) placing the ipsilateral attachment system of the bifurcated prosthesis into the ipsilateral capsule means;
- (e) placing the contralateral attachment system of the bifurcated prosthesis into the contralateral capsule means;
- 15 (f) placing the bifurcated prosthesis and the delivery means into the capsule jacket means;
- (g) creating an opening in the corporeal lumen for traversing the capsule jacket means, the delivery means and the bifurcated prosthesis therethrough;
- 20 (h) inserting the capsule jacket means, the delivery means and the bifurcated prosthesis into the opening in the corporeal lumen;
- (i) urging the bifurcated prosthesis to a desired location within the corporeal lumen;
- 25 (j) positioning the distal capsule means at a desired location within the corporeal lumen;

-81-

- (k) activating the superior attachment system to secure the superior end of the bifurcated prosthesis within the corporeal lumen;
- 5 (l) positioning the contralateral capsule means at a desired location within the corporeal lumen;
- (m) activating the contralateral attachment system to secure the contralateral end of the bifurcated prosthesis within the corporeal lumen;
- 10 (n) positioning the ipsilateral capsule means at a desired location within the corporeal lumen;
- (o) activating the ipsilateral attachment system to secure the ipsilateral end of the bifurcated prosthesis within the corporeal lumen;
- 15 (p) removing the delivery means from the corporeal lumen; and
- (q) closing the opening in the corporeal lumen.

32. The method of claim 31, said method further comprising the steps of:

- 5 (r) withdrawing the capsule jacket means proximally to expose the distal capsule means, bifurcated prosthesis, contralateral capsule means and at least a portion of the ipsilateral capsule means after performing step (i) and prior to performing step (j);
- (s) removing the superior attachment system from the distal capsule means after performing step (j) and
- 10 prior to performing step (k);

-82-

- (t) removing the contralateral attachment system from the contralateral capsule means after performing step (l) and prior to performing step (m); and
- (u) removing the ipsilateral attachment system from the ipsilateral capsule means after performing step (n) and prior to performing step (o).

5